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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,209

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Julie Hazel Campbell

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EXAMINER

TSAY, MARSHA M

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/530,209	<b>Applicant(s)</b> CAMPBELL ET AL.	
	<b>Examiner</b> Marsha M. Tsay	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/24/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

This Office action is in response to Applicants' remarks received December 31, 2007.

Claims 13-16 are canceled. Claims 1-12 are pending and currently under examination.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Priority: The priority date is October 4, 2002 for the purpose of prior art.

### **Objections and Rejections**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott et al. (WO 0100047; IDS). Elliott et al. disclose a method for reducing the incidence of cardiovascular disease and peripheral vascular disease comprising the steps of manufacturing and administering a dietary supplement in the form of a milk product including A<sup>2</sup>  $\beta$ -casein but substantially no A1 or B  $\beta$ -casein (p. 10-11 lines 307-311). Elliott et al. also disclose that both Type I and Type 2 diabetes increase the risk of coronary heart disease (p. 20 lines 577-578). In Experiment 1, Elliott et al. disclose the administration of Prosobee (soy preparation used as rat food) plus 10% type A<sup>2</sup>  $\beta$ -casein to study the incidence of diabetes (p. 13-14 lines 389-406; claims 1-11). Elliott et al. disclose the  $\beta$ -casein A<sup>2</sup> can be obtained from *Bos indicus*, Icelandic

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dairy cows, goats (p. 23 lines 665-667; claim 12). Elliott et al. disclose food products made from type A<sup>2</sup>  $\beta$ -casein, including yogurt, cheese, wherein the  $\beta$ -casein A<sup>2</sup> can be fortified with additional compounds (p. 22 lines 637-655; claims 8, 13-16). Elliott et al. do not explicitly teach the oral administration of  $\beta$ -casein A<sup>2</sup> to a mammal for reducing cholesterol.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to orally administer the  $\beta$ -casein A<sup>2</sup> supplement of Elliott et al. to a patient for reducing cardiovascular disease and associated conditions, such as high cholesterol because Elliott et al. disclose a milk product comprising solely of  $\beta$ -casein A<sup>2</sup> can be manufactured and administered as a dietary supplement for reducing cardiovascular disease and peripheral vascular disease (claims 1-16).

While Elliott et al. do not explicitly teach the elements of reducing cholesterol, apolipoprotein B, triglycerides, hypercholesterolemia, hyperlipidemia, atherosclerosis or that said  $\beta$ -casein is at least 95%  $\beta$ -casein A<sup>2</sup>, these elements are believed to be unpatentable over Elliott et al. because Elliott et al. disclose the supplement comprises  $\beta$ -casein A<sup>2</sup> but substantially no A1 or B  $\beta$ -casein. Therefore, one of ordinary skill would recognize that the  $\beta$ -casein of Elliott et al. comprises solely of  $\beta$ -casein A<sup>2</sup> and at least 95%  $\beta$ -casein A<sup>2</sup>. Regarding the elements of reducing cholesterol, apolipoprotein, triglycerides, hypercholesterolemia, hyperlipidemia, and atherosclerosis, one of ordinary skill would recognize that these are factors that are strongly correlated with an increased risk of heart disease, and are unpatentable over Elliott et al. because Elliott et al. disclose a method for reducing the incidence of cardiovascular disease by administering  $\beta$ -casein A<sup>2</sup>; and therefore, it would be reasonable to expect that said elements would be reduced upon administration of  $\beta$ -casein A<sup>2</sup> into a patient.

In their remarks, Applicants assert that ELLIOTT et al. also discuss the correlation between the incidence of Type I diabetes and the consumption of  $\beta$ -casein variants A and B (through milk consumption). ELLIOTT et al. say that a dietary supplement fortified by a component such as folic acid and including milk or a milk product having a p-casein content which is substantially p-casein A<sup>2</sup> is capable of reducing vascular diseases. ELLIOTT et al. discuss (see second paragraph on page 13) that the compositions are intended to reduce the incidence of vascular disease and to reduce the incidence of diabetes. ELLIOTT et al. clearly says that the reduction of vascular disease is "directly through the use of tHcy reducing agents" and indirectly by reducing the incidence of diabetes through (a) provision of bovine milks high in the A2 variant of beta-casein and low in A1 and B variants, and/or (b) exploitation of the immunological properties of beta-casomorphin 9." ELLIOTT et al. fail to teach or infer that serum levels of cholesterol, LDL cholesterol, VLDL cholesterol, apolipoprotein B, and triglycerides can be influenced by  $\beta$ -casein A<sup>2</sup> or BCM, with the biological action of the latter described in ELLIOTT et al. as an immunomodulator. Applicants' remarks have been fully considered but they are not persuasive.

On pages 10-11, Elliott et al. clearly disclose that  $\beta$ -casein A<sup>2</sup> can be provided as a supplement to reduce the incidence of cardiovascular disease in a population (lines 307-311). Elliott further disclose  $\beta$ -casein A<sup>2</sup> can be called a "heart milk" (p. 24 line 699) and that specific benefits include vascular disease reduction as expressed in heart disease mortality (p. 24 line 707). On page 1, Elliott et al. disclose that vascular disease refers to coronary heart disease (CHD) (lines 8-10). It is well known in the art that factors associated with coronary heart disease

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include high levels of cholesterol, triglycerides, bad LDL, low levels of good HDL (MedlinePlus and emedicine reference pages). Therefore, it would be reasonable for one of ordinary skill to recognize that if administering  $\beta$ -casein A<sup>2</sup> can reduce the incidence of coronary heart disease, then the risk factors associated with coronary heart disease would also be reduced, i.e. serum levels of cholesterol, LDL cholesterol, VLDL cholesterol, apolipoprotein B, and triglycerides.

Regarding Applicants' assertion that ELLIOTT et al. clearly says that the reduction of vascular disease is "directly through the use of tHcy reducing agents" and indirectly by reducing the incidence of diabetes through (a) provision of bovine milks high in the A2 variant of beta-casein and low in A1 and B variants, and/or (b) exploitation of the immunological properties of beta-casomorphin 9." Regarding (a), it should be noted that on page 12, Elliott et al. disclose that the milk comprising  $\beta$ -casein A<sup>2</sup> can be optionally formulated with tHcy-reducing compounds that will significantly reduce diabetes and vascular disease. Therefore, it would be reasonable for one of ordinary skill to recognize that the tHcy-reducing compounds (if added) would directly reduce vascular disease and thus, are added to further enhance the beneficial effects of  $\beta$ -casein A<sup>2</sup>, i.e. reducing diabetes and coronary heart disease. Regarding (b), Elliott et al. disclose beta-casomorphin 9 as an active and relatively stable peptide digest fraction of  $\beta$ -casein A<sup>2</sup>, having nine amino acids (p. 13 lines 380-381). Since Elliott et al. already disclose the administration of  $\beta$ -casein A<sup>2</sup> to a mammal, the functional limitation and/or the mechanism of how it does what it does is not relevant since the ingested  $\beta$ -casein A<sup>2</sup> has the overall effect of reducing diabetes and coronary heart disease.

For these reasons, the Elliott et al. reference is maintained.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

April 17, 2008